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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER THER.010US1 U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/533350 |
| INTERNATIONAL APPLICATION NO. PCT/US2003/035343 | INTERNATIONAL FILING DATE 5 November 2003 | PRIORITY DATE CLAIMED 5 November 2002 |
| TITLE OF INVENTION Assay Device, System and Method | | |
| APPLICANT(S) FOR DO/EO/US Arvind N. Jina and TheraSense, Inc. | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input checked="" type="checkbox"/> A preliminary amendment. 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A power of attorney and/or change of address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: <u>Express Mail#: EV438839373US, Return Postcard and Comments Regarding Abstract, Amended Claims under</u> | | |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/533350 | | INTERNATIONAL APPLICATION NO. PCT/US2003/035343 | | ATTORNEY'S DOCKET NUMBER THER.010US1 | |
| The following fees have been submitted | | | | CALCULATIONS | PTO USE ONLY |
| 21. <input checked="" type="checkbox"/> Basic national fee..... \$300 | | | | \$ 300 | |
| 22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$100 All other situations..... \$200 | | | | \$ 200 | |
| 23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500 | | | | \$ 100 | |
| TOTAL OF 21, 22 and 23 = | | | | \$ 600 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| - 100 = | 0 /50 = | 0 | x \$250 | \$ 0 | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)). | | | | \$ 130 | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | \$ | |
| Total claims | 85 - 20 = | 65 | x \$ 50 | \$3,250 | |
| Independent claims | 4 - 3 = | 1 | x \$200 | \$ 200 | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | + \$360 | \$ 360 | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$3,940 | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | | |
| SUBTOTAL = | | | | \$4,540 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | \$4,540 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | | | \$ | |
| TOTAL FEES ENCLOSED = | | | | \$4,540 | |
| | | | | Amount to be refunded: | \$ |
| | | | | Amount to be charged: | \$ |
| a. <input checked="" type="checkbox"/> A check in the amount of \$4,540.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>502664</u> . A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. | | | | | |
| NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status. | | | | | |
| SEND ALL CORRESPONDENCE TO: | | | | | |
|  SIGNATURE K. Alison de Runtz NAME 37,119 REGISTRATION NUMBER | | | | | |

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10/533350
JC20 Rec'd PCT/PTO 29 APR 2005

September 16, 2004

EXPRESS MAIL # EV 438839135 US

MAIL STOP PCT
ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: International Appl. No.: PCT/US2003/035343
International Filing Date: 5 November 2003
Applicant: TheraSense, Inc.
Title: Assay Device, System And Method
Our Ref.: THER.010WO0

Sir:

COMMENTS REGARDING ABSTRACT

This letter is a submission regarding the abstract text established by the International Searching Authority (PCT/ISA/210), as set forth in the *Notification of Transmittal of the International Search Report of the Declaration*, dated 19 August 2004.

It is noted that the International Searching Authority has established a new abstract, as the original abstract did not include reference signs between parentheses. In a review of the new abstract, however, it was noted that the new abstract contains typographical, spelling, and/or grammatical errors that did not appear in the original abstract (for example, "elease" instead of "release"; "a results" instead of "a result"; and, in two instances, "anlyte" instead of "analyte"); describes a particular system with reference to Figure 5B, when that particular system is not fully shown in Figure 5B alone; and does not include reference signs for a number of features described. Thus, it is respectfully requested that the abstract read as set forth below, as fully supported by the original abstract and the original specification.

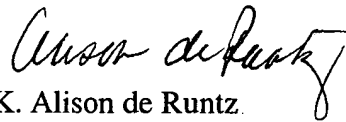
A system for treating a blood sample (700) having an analyte of interest comprises a strip (200) having a membrane (218), respective portions (216, 220 and 222, or 300) which are provided for receiving the sample, for lysing

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cells of the sample to liberate hemoglobin, and for capturing glycated hemoglobin. The latter two portions (220 and 222, or 300) of the membrane are treated with lysing and capture agents, respectively. A portion of the strip (214 or 230 or 240) is provided for holding an eluting agent and for releasing the agent upon a release condition. A system for detecting analyte comprises an optical subsystem (550) that is aligned with the strip to provide a signal corresponding to an amount of analyte, and an electronic subsystem (650) for processing the signal (560) to provide a result, such as an amount or percentage of glycated hemoglobin. To use these systems, the user simply applies a small sample (700) to the membrane (218) and closes a door (10) of the detection system over the strip (200) such that the door triggers the release of the eluting agent. No sample pre-treatment is required. The preferably handheld system (100) is a simple and convenient monitoring tool for the user, such as a diabetic patient who must monitor blood glucose on an on-going basis. While the systems are useful in the monitoring of blood glucose, they may be used for treating a sample other than blood and detecting an analyte other than an analyte in blood.

A replacement page of the abstract is submitted herewith.

Respectfully submitted,



K. Alison de Runtz
Reg. No. 37,119

Enclosure